K023350

NOV 6 2002

6 510(k) SUMMARY

Company Information:	Respironics, California Inc. 2271 Cosmos Court Carlsbad, CA. 92009
Contact:	Mary Funk Regulatory Affairs Project Manager Phone Number: (760) 918-7328 Fax Number: (760) 918-0169
Date Prepared:	November 5, 2002
Product Name:	Esprit Ventilator with Respiratory Mechanics
Classification:	Class II Continuous Ventilator (per 21 CFR 868.5895) Diagnostic Spirometer (per 21 CFR 868.1840)

Predicate Devices:		
	Puritan-Bennett 7200a Ventilator	K902506
	Puritan-Bennett 840 Ventilator	K970460
	Infrasonics Adult Star Ventilator	K905272
	Dräger Evita 4 Ventilator	K961687
	Respironics BiPAP Vision	K982454

Description of Device Modification:

Esprit Respiratory Mechanics is a diagnostic tool that enables a clinician to take dynamic and static measurements of a patient's lung parameters. The following maneuvers can be performed using Esprit Respiratory Mechanics:

- Vital Capacity
- Maximum Inspiratory Pressure
- PO.1 (Pressure change after the first 100 milliseconds of inspiratory effort)
- Static Compliance and Resistance

These tools are used by clinicians to monitor a patient's respiratory status and are displayed on the Esprit User Interface both graphically and in text format. Respiratory Mechanics also calculates the following:

- Ti/Ttot
- Peak Lung Flow
- Dynamic Compliance and Resistance

Intended Use:

The Esprit ventilator is a microprocessor controlled, electrically powered, mechanical ventilator. It is intended for use by qualified medical personnel in providing continuous or intermittent ventilatory support to adult and pediatric patients as prescribed by a physician. The Esprit Ventilator is intended for use in either invasive or non-invasive applications.

Esprit is not intended for use in the presence of flammable anesthetics. Esprit is a prescription use device that is intended for sale by or on the order of a physician.

Technological Characteristics:

The Esprit ventilator does not incorporate any new technological characteristics with the addition of Respiratory Mechanics.

Determination of Substantial Equivalence:

The Esprit Ventilator with Respiratory Mechanics has similar performance characteristics, the same intended use, the same environment of use and patient populations as the currently marketed predicate devices. The labeling and instructional information, including warning and caution statements, is similar to that of the predicate devices. The addition of this new feature does not raise new questions of safety or effectiveness for the Esprit.

Summary of Performance Testing:

Software validation testing was performed in accordance with FDA's Guidance for the Content of Premarket Submissions for Software contained in Medical Devices (1998). The results of all verification and validation testing demonstrate that all design and system requirements for the Esprit ventilator with Respiratory Mechanics have been met.

Conclusion:

The technological characteristics of the Esprit ventilator with Respiratory Mechanics and the results of the performance testing do not raise new questions of safety and effectiveness when compared to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 6 2002

Ms. Mary Funk
Regulatory Affairs Project Manager
Respironics California, Incorporated
Hospital Division
2271 Cosmos Court
Carlsbad, California 92009

Re: K023350
Trade/Device Name: Esprit Ventilator with Respiratory Mechanics
Regulation Number: 21 CFR 868.5895 and 21 CFR 868.1840
Regulation Name: Continuous Ventilator and Diagnostic Spirometer
Regulatory Class: II
Product Code: CBK and BZG
Dated: October 4, 2002
Received: October 7, 2002

Dear Ms. Funk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k): Device Modification
Esprit Ventilator with Respiratory Mechanics

8 STATEMENT OF INDICATIONS FOR USE

Applicant: Respironics California, Inc.

510(k) Number: K023350

Device Name: Esprit Ventilator with Respiratory Mechanics

Indications for use: The Esprit ventilator is a microprocessor controlled, electrically powered, mechanical ventilator. It is intended for use by qualified medical personnel in providing continuous or intermittent ventilatory support for adult and pediatric patients as prescribed by a physician. The Esprit Ventilator is intended for use in either invasive or non-invasive applications.

Prescription Use: Yes (Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Per 21 CFR 801.109)
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023352

Prescription Use ✓ or OTC Use _____